EXHIBIT F

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL No. 2327**
	2:12-md-02327
THIS DOCUMENT RELATES TO:	**HON. JOSEPH R. GOODWIN**
Hope Elaine Pridmore, et al. v. Ethicon, Inc.., et al No. 2:12-cv-00878	

RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MD

My name is Konstantin Walmsley. I have been retained by the Motley Rice Law Firm to give medical opinions related to Hope Elaine Pridmore. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae and schedule of previous testimony are attached to this report. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical probability.

I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices.

I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh, including mid urethral slings, and am familiar with the properties of these devices and proper implantation technique for these devices. Further, I am familiar with non-mesh options for the treatment of stress urinary incontinence including the pubovaginal sling. I have attending training

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provided by Ethicon, Inc. regarding the TVT device. I have explanted and performed other revision procedures on transobturator and retropubic mid-urethral slings including the TVT device.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants.

The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, and incomplete emptying), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

I have reviewed the following medical records and depositions with accompanying exhibits pertaining to Hope Elaine Pridmore:

- Franciscan St. Margaret Health Hammond Campus;
- Community Hospital;
- Knox Winamac Community Health Center;
- Lake Urology LLC;
- Munster Medical Center;
- Medical Associates of Highland;
- Centers for Medicare & Medicaid Services (CMS) (Region 5);
- Workers Compensation Board of Indiana;
- St. Catherine Hospital;
- Consultants in Gastroenterology;
- Franciscan Medical Specialists - Hammond;
- Family Health & Wellness Center;
- Jayesh Madhani, M.D.;
- Thomas E. Green;
- Munster Radiology Group;

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- Franciscan Medical Specialists;
- Dalal Medical Corporation;
- Blue Cross Blue Shield of Kentucky Anthem Health Plans;
- Amit Vyas, MD;
- Medical Management & Data Services;
- Emory Saint Joseph's Hospital;
- Alverno Clinical Labs;
- Cardiology Associates of Northwest Indiana PC;
- Norwood Clinic Fultondale Medical Plaza;
- Infectious Disease Specialists;
- Mahendra Shah, M.D.;
- Porter Physician Group- Coffee Creek;
- Advocate Medical Group;
- Community Care;
- Optimum Primary Care, LLC;
- Pathology Consultants Inc.; and
- Chicago Cardiovascular Consultants

In addition to the review of the medical records listed above, I have also reviewed the following medical literature and other TVM related documents and have relied, in part, on the documents below in addition to my medical and clinical experience in forming my opinions:

- AMA 8.08
- TVT Instructions for Use
- C.G. Nilsson et al "Seventeen years' follow-up of the tension free vaginal tape procedure for female stress urinary incontinence." Int. Urogynecol. J. (2013) 24:1265-69
- P. Hilton "A clinical and urodynamic study comparing the Stamey bladder neck suspension and suburethral sling procedures in treatment of genuine stress incontinence" British Journal of Obst. & Gynecol (February 1989, Vol 96, pp. 213-220
- H. Enzelsberger et. al "Comparison of Burch and Lyodura Sling Procedures for Repair of Unsuccessful Incontinence Surgery" Obstet & Gynecol, Vol 88, No. 2, August 1996

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- A.S. Arunkalaivanan et al "Randomized trial of porcine dermal sling (Pelvicol implant) vs. Tension-free Vaginal Tape (TVT) in the Surgical treatment of stress incontinence: a questionnaire based study" Int. Urogynecol J (2003), 14: 17-23
- K. Guerrero et al "A randomized controlled trial comparing two autologous fascial sling techniques for the treatment of stress urinary incontinence in women: short, medium and long-term follow-up" Int. Urogynecol J (2007) 18:1263-1270
- B. Welk et al, "Removal or Revision of Vaginal Mesh Used for the Treatment of Stress Urinary Incontinence" JAMA Surgery, Published Online September 9, 2015.
- E. Petri et al., "Complications of synthetic slings used in female stress urinary incontinence and applicability of the new IUGA-ICS classification" Eur. J. of Obstet. & Gynecol. and Reprod. Bio. 165 (2010) 347-351
- B. Klosterhalfen et al., "Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair" Biomaterials (1998) 2235-46
- J. Anger et al., "Complications of Sling Surgery Among Female Medical Beneficiaries" Obstet. & Gynecol. Vol. 109, No. 3 (March 2007)
- P. Moalli et al, "Tensile Properties of five commonly used mid-urethral sling relative to the TVT" Int. Urogynecol J (2008) 19:655-663
- A. Clave et al, "Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants" Int. Urogynecol J (2010) 21:261-270
- O. Chinthakanan et al., "Mesh Removal Following Sling/Mesh Placement: A Multicenter Study" Int. Urogynecol. J (2014) 25 (Suppl 1) S-139-40
- O. Chinthakanan et al, "Indication and Surgical Treatment of MidUrethral Sling Complications: A Multicenter Study" Int. Urogynecol. J (2014) 25 (Suppl 1) S-142-43
- E. Petri et al., "Comparison of late complications in retropubic and transobturator slings in stress urinary incontinence" Int. Urogynecol. J. (2012) 23:321-325

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- S. Abbott et al., "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study" American J. of Obstet. & Gynecol (February 2014) 163.e1-8.
- G. Agnew et al, "Functional outcomes following surgical management of pain, exposure or extrusion following a suburethral tape insertion for urinary stress incontinence" Int. Urogynecol J. (2014) 25:235-239
- J. Duckett et al, "Pain after suburethral sling insertion for urinary stress incontinence" Int. Urogynecol J. (2013) 24:195-201
- C. Skala et al., "The IUGA/ICS classification of complications of prosthesis and graft insertion" Int. Urogynecol J (2011) 22:1429-1435
- K. Svabik et al., "Ultrasound appearances after mesh implantation -- evidence of mesh contraction or folding?" Int. Urogynecol J. (2011) 22:529-533
- A. Rogowski et al., "Mesh retraction correlates with vaginal pain and overactive bladder symptoms after anterior vaginal mesh repair" Int. Urogynecol. J. (2013) 24:2087-2092

Clinical History

- In June of 2007, Mrs. Pridmore saw Dr. Howard Diamond with complaints of mixed urinary incontinence. She had a prior history of recurrent urinary tract infections (UTIs) and was being treated for urgency urinary incontinence with Vesicare. She also had a history of a Marshall-Marchetti-Krantz procedure done many years back for incontinence. More recently, however, she had complaints of worsening stress urinary incontinence. Physical examination and cystoscopy were suggestive of urethral hypermobilty and cystocele. She was counseled towards surgical repair.

- On September 4th, 2007, Ms. Pridmore underwent insertion of a TVT-O sling by Dr. Diamond. The procedure was somewhat challenging given the patient's obesity but proceeded otherwise uneventfully. Dr. Diamond made sure to avoid any sling wrinkling or twisting and describes setting the tension under the urethra so that the sling was just snug.

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- On October 15th, 2007, she saw Dr. Diamond post-operatively. Her stress incontinence had resolved. She had complaints of urgency and urgency urinary incontinence as well as urethral burning.

- On December 7th, 2009, she saw Dr. Diamond and underwent cystoscopy. No significant findings were memorialized.

- On April 12th, 2010, she saw Dr. Diamond once again with a UTI and continued incontinence.

- On May 10th, 2010, she was prescribed further antibiotics for a UTI by Dr. Diamond.

- On September 28th, 2010, she was prescribed Oxybutynin for her urinary urgency symptoms by Dr. Diamond.

- On October 10th, 2010 she was diagnosed and treated for a UTI by Dr. Diamond.

- On November 17th, 2011, she was admitted to Community Hospital because of dysphagia and a UTI. She seen during her hospital stay by Dr. Hasson Alsheik. He memorialized that since her sling surgery performed by Dr. Diamond, she had been having worsening pain, as well as frequency, urgency, and recurrent urinary tract infections. He performed cystoscopy and biopsy of a bladder lesion that turned out to be non-cancerous. Her urethra and bladder neck were wide open. She had expressed an interest in sling removal during her hospitalization.

- On September 10th, 2012, she was admitted to Community Hospital with generalized weakness and was found to have an ESBL E. Coli UTI.

Methodology

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My general opinions are based upon my clinical experience and review of medical and scientific literature and well as my medical education, knowledge, training, practice, and clinical experience.

My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause.

General Opinion No. 1

Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a given procedures – including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

It is my opinion the IFU for the TVT in 2007 was not sufficient to enable informed consent from the patient. The TVT IFU provided:

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.

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- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The words "transitory" and "transient" carry a specific medical meaning. Mosby's medical dictionary defines transient as "pertaining to a condition that is temporary." Using the word transient to describe the human body's foreign body response to the TVT mesh implies the response dissipates with time. In my experience, this does not accurately describe the human body's foreign body response to transvaginal placed mesh.

In my experience when dealing with synthetic mesh-induced foreign body response, the degree of inflammation and scarring around the mesh is intense and chronic. More often than not, when removing exposed mesh, I am unable to completely remove the entire mesh implant because of the intensity of inflammation and extensive scarring induced by mesh incorporation into the host tissues. Moreover, in all of my experiences removing mesh, residual scarring of the vagina and peri-vaginal tissues persists and is even more severe in the instances where residual pelvic mesh is left in the patient.

The TVT IFU does not mention: mesh contraction; dyspareunia; mesh shrinkage; scar plate formation; or the difficulty in removing mesh in the event of an adverse event. These events are all part of my informed consent conversation today. I have treated patients implanted with mid-urethral slings, including the TVT for these conditions. These events were reported in the mid-urethral sling literature prior to when Mrs. Pridmore was implanted. In my opinion, a patient considering a mid-

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urethral sling cannot be properly consented without discussing these potential adverse events.

General Opinion No. 2

Safer alternatives designs and procedures existed in 2007 that have a lesser risk of pelvic pain and scarring with substantially equivalent efficacy.

Case Specific Opinion No. 1

Mrs. Pridmore's vaginal pain and voiding dysfunction were caused by scarring following insertion of the TVT device as well as chronic and persistent infections following sling insertion. The differential diagnosis for vaginal pain after synthetic sling surgery are similar to that of dyspareunia and would include: (1) erosion/extrusion; (2) mesh contraction; (3) scarring with reduced elasticity; (4) infection and inflammation including but not limited to vestibulitis; (5) neuromuscular injury (6) lichen sclerosis; (7) vaginal tissue atrophy; and (8) pelvic floor dysfunction.

I am able to rule out erosion, extrusion, lichen sclerosis, vaginal tissue atrophy, or pelvic floor dysfunction as potential causes of Mrs. Pridmore's vaginal pain as there is no documentation of any of these conditions in the medical records I've reviewed.

I am not able to rule in mesh contraction as a potential cause of Mrs. Pridmore's vaginal pain as there is no memorialization of this finding in the medical records.

I am able to rule in scarring with reduced elasticity as a cause of Mrs. Pridmore's vaginal pain. This is supported by the severity of voiding dysfunction symptoms she developed following her TVT-O surgery. Although she had symptoms of overactive bladder and urgency urinary incontinence prior to her sling surgery, her symptoms significantly worsened following her surgery with Dr. Diamond. Of note, Dr. Alsheik's cystoscopy revealed no obstructive pathology related to Mrs. Pridmore's sling. The severity of these symptoms and the chronology of their

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development soon after her sling was implanted rules in scarring with reduced elasticity as a likely cause of her vaginal pain

I am able to rule in infection and inflammation as causative factors relating to Mrs. Pridmore's vaginal. Although she had a history of UTIs pre-sling, the frequency and severity of her UTIs post-sling were much different and more severe, in one instance requiring hospitalization. These infections were also often resistant and more difficult to treat as a result.

Case Specific Opinion No. 2

Mrs. Pridmore's future prognosis as it relates to her vaginal pain and voiding dysfunction is guarded. Because she has pelvic mesh still inside of her body, she will continue to suffer from vaginal pain and recurrent infections. Even if she were to have all of her mesh removed, the surgery require to execute this procedure is extensive, complicated, and almost exclusively performed in tertiary academic centers. I anticipate that if heroic surgery were performed to remove all of her mesh that she would develop further scarring and fibrosis inherent to this procedure.

In as much an autologous fascial sling or other procedures (not involving synthetic mesh) for incontinence might be considered if her mesh were to be removed, these would be challenging because of the fibrosis and scarring present form her TVT-O procedure. Autologous fascial slings placed in the setting of scar tissue, a likely finding given prior anti-incontinence procedures, would have a lower success rate and a higher complication rate than if it were performed in the absence of scarring. For this reason, Mrs. Pridmore is not an ideal candidate for this type of surgery and is likely best treated with medical therapy in combination with lifestyle modifications and pelvic floor physiotherapy. Although these interventions should be somewhat helpful, they most certainly will not resolve the voiding dysfunction she currently suffers from.

In summary, within a reasonable degree of medical certainty, the voiding dysfunction, and vaginal pain will be a lifelong condition for this patient.

Sincerely,

Konstantin Walmsley, M.D.